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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/040,830      | 01/08/2002  | Gary E. Borodic      | 33677-00000         | 2713             |

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EXAMINER

FORD, VANESSA L

ART UNIT PAPER NUMBER

1645

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/040,830 | <b>Applicant(s)</b><br>BORODIC ET AL. |  |
|                              | <b>Examiner</b><br>Vanessa L. Ford   | <b>Art Unit</b><br>1645               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/20/2005</u> | 6) <input type="checkbox"/> Other: _____   |

S.O.D.

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and response filed April 20, 2005 is acknowledged. Claim 16 has been amended.

### ***Rejection Withdrawn***

2. In view of Applicant's remarks the rejection of claims 16-19 under 35 U.S.C. 102(e) (Aoki et al), pages 2-4, paragraph 4 of the Final Office has been withdrawn.

For clarification of the record the Binder reference is used as an anticipatory reference under **35 U.S.C. 102(b)** and not 35 U.S.C. 102(e).

Art Unit: 1645

***Rejection Maintained***

3. The Applicant's arguments regarding the rejection of claims 16-19 under 35 U.S.C. 102(e) were addressed on pages 4-6, paragraph 5 of the Final Office Action.

The rejection was on the grounds that Binder teaches a method of treating pain caused by trigeminal neuralgia by delivering an invertebrate presynaptic neurotoxin (botulinum toxin A) to a mammal (see the Abstract). Binder teaches that the botulinum toxin A is administered to the muscles of the face, cranium and neck (see the Abstract). Binder teaches that neurotoxin can be administered in a dose up to about 1000 units although individual dosages of about 15-30 units are preferred and dosages of 2.5 to 5 units will have therapeutic efficacy. Binder teaches that the neurotoxin will be administered as a composition at a dosage that is proportionally equivalent to about 2.5 cc/100 units (see columns 5-6). The claim limitation "wherein the neuralgia is associated with trauma" would be inherent in the teaching of the prior art because trigeminal neuralgia is associated with trauma and pain. Binder anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that headache pain is not the same as facial pain caused by trigeminal neuralgia. Applicant urges that Binder is directed to treating headache pain, not facial pain caused by trigeminal neuralgia. Applicant urges that there is simply no teaching or suggestion anywhere in any reference of record that facial pain caused by trigeminal neuralgia can or even should be treated using botulinum toxin. Applicant urges that methods of treating facial pain caused trigeminal neuralgia using the recited dosages (claim 18) are not taught or suggested in Binder. Applicant urges that the rejection is improper and should be withdrawn.

Art Unit: 1645

Applicant's arguments filed April 20, 2005 and in-person interview held June 14, 2005 have been fully considered but they are not persuasive. The claims are directed to a method of treating facial pain caused by trigeminal neuralgia comprising administering to a patient in need thereof multi-focal injections of a therapeutically effective amount of botulinum toxin to an afflicted area of the face, excluding the brow and upper or lower eyelid, of said patient, thereby reducing or eliminating said facial pain caused by trigeminal neuralgia. Webster's II New Riverside University Dictionary defines "trigeminal neuralgia" as an intensively painful inflammation of the facial area around the trigeminal nerve. Stedman's Medical Dictionary, 24<sup>th</sup> Edition defines "trigeminal nerve" as the fifth cranial nerve. Binder teaches that trigeminal neuralgia is associated with cranial and facial nerves and trigeminal neuralgia is also commonly associated with headaches (Table 1(b), column (2)). Binder teaches a method of alleviating pain from local areas of the face including relief of headache as well as such trigeminal neuralgia by administration of botulinum toxin (column 6, lines 58-67; column 7, lines 1-3; Table 1(b), (column 2). Binder teaches that a therapeutically effective amount of neurotoxin (botulinum toxin) is administered by extramuscular injection to the perimuscular areas of the face, cranium and neck (column 4). Binder teaches a therapeutically effective amount of neurotoxin (botulinum toxin) is administered by extramuscular injection to the perimuscular areas of the face, cranium and neck (column 4). Binder teaches that reduction of headache pain was unexpectedly observed even in patients whose pain was causally related to vascular or neurological components; e.g., classical migraine, trigeminal neuralgia and trauma headache (column 6, lines 58-67 and column 7, lines 1-

Art Unit: 1645

3). Therefore, one skilled in the art would recognize that botulinum toxin can be used to treat headaches as well as trigeminal neuralgia since trigeminal neuralgia is caused by inflammation of cranial nerves and Binder et al teaches that additional therapeutic benefits can be expected from administration of the presynaptic neurotoxin of the invention into one or more striated muscles of the face, cranium and/or neck (column 4). It should be noted that Figure 1 of the prior art reference discloses botulinum toxin can be administered to various areas of the face. Preferred target areas include the bilateral temporal, frontal, glabella and suboccipital areas of the face (column 7).

To address Applicant's comments regarding that the dosages used in the claimed method are not recited in the prior art reference, it should be noted that Binder teaches that up to 40 units botulinum toxin can be administered to a patient depending on the site of injection (column 6). Thus, the prior art reference administers a therapeutically effective amount of botulinum toxin that is within the range recited in the claimed method. There is nothing on the record to show that the claimed method differs from that of the prior art. Therefore, the teachings of Binder anticipate the claimed method.

### ***New Grounds of Rejection***

#### ***Claim Objection***

4. Claim 18 is objected to for the following informalities: "about 10 to 200 LD 50 units" should be "about 10 to 200 LD<sub>50</sub> units" since Applicant appears to be referring to lethal dose.

***Specification***

5. The disclosure is objected to because of the following informalities:

The use of the trademarks has been noted in this application. See for example, page 9. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate correction is required.

***Status of Claims***

6. No claims allowed.

Art Unit: 1645

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Vanessa L. Ford  
Biotechnology Patent Examiner  
July 7, 2005



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